



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: Science Review in Support of the Registration of the TGA/MP Product Bedoukain Z-11-Hexadecenal Technical Pheromone (EPA File Symbol No. 052991-RU), containing 93.0% Z-11-Hexadecenal (Chemical No. 120001) as its Active Ingredient. Review of Product Chemistry Studies. DP Barcode D267371; Case No. 068834; Submission No. S581964; MRID No. 451223-01.

FROM: Russell S. Jones, Ph.D., Biologist
Biochemical Pesticides Branch
Biopesticides & Pollution Prevention Division (7511C)

THRU: Freshteh Toghrol, Ph.D., Senior Scientist
Biochemical Pesticides Branch
Biopesticides & Pollution Prevention Division (7511C)

TO: Andrew Bryceland, Regulatory Action Leader
Biochemical Pesticides Branch
Biopesticides & Pollution Prevention Division (7511C)

ACTION REQUESTED

Bedoukian Research, Inc. requests registration of the TGA/MP product, Bedoukain Z-11-Hexadecenal Technical Pheromone (EPA File Symbol. No. 52991-RU) containing 93% Z-11-hexadecenal as its active ingredient. In support of the registration, the registrant has submitted product chemistry studies (MRID No.451223-01), a Confidential Statements of Formula (CSF; dated 6/19/2000) for the basic formulation, and a proposed label.

CONCLUSIONS AND RECOMMENDATIONS

1. Product chemistry data submitted for product identity and composition (151-10), discussion of the formation of impurities (151-12), preliminary analysis (151-13), and physical chemical properties (151-17) are acceptable. No additional data are required for these guidelines.

2. The manufacturing process (151-11) is unacceptable. An intentionally added ingredient, listed as an [REDACTED] on the CSF (dated 6/19/00), is not discussed in the description of the manufacturing process. This discrepancy must be resolved.
3. The certified limits data (151-15) are unacceptable. The certified limits data for the intentionally added ingredient used as an [REDACTED] cannot have a lower limit of [REDACTED] of the product by weight. This discrepancy must be resolved. The certified limits listed on the CSF for this ingredient must also be revised.
4. The analytical method (151-16) is acceptable pending submission of an acceptable limit of detection.

LABEL REVIEW

The label contains the signal word "CAUTION", which is appropriate for manufacturing use products classified in Toxicity Categories III or IV. It also contains appropriate precautionary statements indicating that the manufacturing-use product may be harmful if swallowed or inhaled and to avoid contact with skin, eyes, or clothing. The first aid statements are also appropriate for Toxicity Category III. To mitigate any potential environmental concerns, the label contains appropriate environmental hazards statements to keep the product out of lakes, ponds, or streams, and to not contaminate water by disposal of wastes.

STUDY SUMMARY

Product Chemistry

The TGAI/MP product consists of one basic formulation. The active ingredient is a straight-chain, 16-C lepidopteran pheromone (Z-11-Hexadecenal) which comprises 93% (by percent weight) of the product. The manufacturing process is not acceptable because it does not discuss an intentionally added ingredient that is used as an [REDACTED] although this ingredient is listed on the CSF. The discussion of the formation of impurities, and the preliminary analysis data are acceptable. The certified limits for the intentionally added ingredient used as an [REDACTED] were unacceptable; the lower limit for an intentionally added ingredient cannot be [REDACTED]. An acceptable analytical method for the determination of the active ingredient in the product was submitted, but no limits of detection data were reported. These data must be submitted when they become available for inclusion into the product data file. Acceptable physical/chemical properties data were submitted and are listed below:

Property	Manufacturing-use Product (MP)
Color:	Colorless to pale yellow
Physical state:	Clear liquid
Odor:	Fatty
Melting point	Not applicable (NA)
Boiling point	Approx. 145°C at 0.2 mm Hg
Density/Specific gravity	Approx. 0.85 gm/mL
Solubility	6.8×10^{-8} mol/L (estimated) at 25°C in water
Vapor pressure	3.9×10^{-5} mm Hg at 25°C
Octanol/water partition coefficient	$K_{ow} = 2.5 \times 10^{-5}$ (estimated)
pH	NA
Flammability	Flash point >230°C
Storage stability	Stable under normal storage conditions for a minimum of 1 year
Corrosion characteristics:	Non-corrosive

NOTE: Physical/chemical characteristics are estimates. No analytical methods or experimental data were submitted.

Classification: Unacceptable, but upgradable pending resolution of the deficiencies described in Conclusions 2, 3, and 4.

cc: F. Toghiani, R. S. Jones, A. Bryceland, BPPD Subject File
R. S. Jones: F.T. CM2, (703) 308-5071: 12/11/2000

~~THE FOLLOWING PAGES CONTAIN CONFIDENTIAL BUSINESS INFORMATION~~

DATA EVALUATION REPORT

Reviewed by: Russell S. Jones, Ph.D. BPPD
Secondary Reviewer: Freshteh Toghrol, Ph.D. BPPD

STUDY TYPE: Product Chemistry (Subdivision M Guidelines 151-10 to 151-17)

DP BARCODE: D267371

CASE No. 068834

SUBMISSION No.: S581964

PC CODE: 120001

TOX. CHEM. No.: None

MRID Nos: 451223-01

TEST MATERIAL: Bedoukian Z-11-Hexadecenal Technical Pheromone (containing 93% active ingredient)

STUDY Nos: None

SPONSOR: Bedoukian Research, Inc., 21 Finance Drive, Danbury, CT 06810-4192

TESTING FACILITY: Bedoukian Research, Inc., 21 Finance Drive, Danbury, CT 06810-4192

TITLES OF REPORTS: Product Chemistry of Bedoukian Z-11-Hexadecenyl Acetate Technical Pheromone

AUTHOR: Robert E. Mahoney

REPORTS ISSUED: June 19, 2000

QUALITY ASSURANCE: The product chemistry studies were not conducted under Good Laboratory Practice (GLP) standards, but standards at the performing laboratory followed the intent of the GLPs. Non-compliance statements in were signed by sponsor/submitter.

Manufacturing process information may be entitled to confidential treatment

Inert ingredient information may be entitled to confidential treatment

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SUMMARY: The TGAI/MP product consists of one basic formulation. The active ingredient is a straight-chain, 16-C lepidopteran pheromone (Z-11-Hexadecenal) which comprises 93% (by percent weight) of the end-use product. The following inert ingredient and manufacturing impurities (by percent weight) are also in the end-use product: [REDACTED]

[REDACTED]. The manufacturing process is not acceptable because it does not discuss an intentionally added ingredient [REDACTED] that is used as an [REDACTED] although this ingredient is listed on the CSF. The discussion of the formation of impurities, and the preliminary analysis data are acceptable. The following certified limits were reported for the active and inert ingredients: [REDACTED]

[REDACTED] and other impurities [REDACTED]. The certified limits for [REDACTED] are not acceptable; the lower limit for this intentionally added ingredient cannot be [REDACTED]. An acceptable analytical method for the determination of the active ingredient in the product was submitted, but no limits of detection data were reported. These data must be submitted when they become available for inclusion into the product data file. Acceptable physical/chemical properties data were submitted.

CLASSIFICATION: Unacceptable, but upgradable. To upgrade the study to acceptable the registrant must assure that [REDACTED] is used in all batches of the product, revise the certified limits for [REDACTED] (when used), and provide limits of detection data for the analytical method.

I. PRODUCT IDENTITY AND DISCLOSURE OF INGREDIENTS (151-10)

A. Z-11-Hexadecenal

Ingredient: Active

Supplier: Bedoukian Research Inc., 21 Finance Drive, Danbury, CT 06810

contains:

1. Z-11-Hexadecenal

Ingredient: Active

CAS Number: 53939-28-9

Empirical Formula: $C_{16}H_{30}O$

Chemical Characterization: Lepidopteran Pheromone

Pages 7-11-*Manufacturing process information may be entitled to confidential treatment*

Manufacturing process information may be entitled to confidential treatment

Inert ingredient information may be entitled to confidential treatment

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variability of the weighing instruments [REDACTED] The nominal concentrations and certified ingredient limits (by % weight) were as follows:

Ingredient		Certified Limits (% by weight)**	
		% by weight	Upper Lower
Z-11-Hexadecenal	95.00	99.90	92.00
[REDACTED]			

*from CSF dated 6/19/2000

VI. ANALYTICAL METHODS (151-16; OPPTS 830.1800)

[REDACTED]

Precision: Method precision was determined via nine analyses of one lot of product on several separate days. A summary of the precision data is presented below:

Analyte	Mean of five analyses	% Relative Standard Deviation
Z-11-Hexadecenal	93.43	0.09
[REDACTED]		

These data, together with the preliminary analysis data, indicate that the method is both precise and accurate. However, no limit of detection was submitted; these data must be submitted.

VII. PHYSICAL AND CHEMICAL CHARACTERISTICS (151-17)

Property	Manufacturing-use Product (MP)
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Octanol/water partition coefficient	$K_{ow} = 2.5 \times 10^{-5}$ (estimated)
pH	NA
Flammability	Flash point >230°C
Storage stability	Stable under normal storage conditions for a minimum of 1 year
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Confidential Statement of Formula may be entitled to confidential treatment